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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,891	11/17/2000	Susan R. Webb	TSRI 536.1Div2	7205

7590

04/08/2003

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EXAMINER

DECLoux, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicant No.

09/715,891

Applicant(s)

WEBB ET AL.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 61-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Applicant's amendment filed 1-21-03 is acknowledged and has been entered.

#### ***Drawings***

The corrected or substitute drawings were received on 1-21-03. These drawings are acceptable.

#### ***Oath/Declaration***

In view of the replacement declarations filed 1-21-03, the objection to the oath has been withdrawn.

#### ***Specification***

In view of the Abstract filed 1-21-03, the objection to the specification has been withdrawn.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

MAINTAINED Claims 61-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

#### ***Response to Arguments***

Applicant traverses the rejection on the grounds that in the Enzo case, the requirement for written description may be satisfied in the knowledge of the art the disclosed function is sufficiently correlated to a particular known structure, and that in Amgen which referred to mammalian and vertebrate cell types that could be used to express recombinant human EPO, the courts found that the words mammalian and vertebrate conveyed distinguishing information that was readily understood by one of ordinary skill in the art. The examiner notes that it is well known in the art that mammalian and vertebrate cell types are suitable hosts for recombinant genes. Applicant contends that the terms of a cell, a MHC Class II heterodimer and an accessory molecule are well known to one of ordinary skill in the art at the time the invention was made. However it is noted that the instant claims are drawn to a method of producing an eucaryotic poikilothermic synthetic antigen presenting cell is not routine as the well practices methods of expressing a foreign gene, such as that encoding EPO, into a mammalian host cell. Applicant

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contends that the specification discloses exemplary cells, NHC Class II genes and heterodimers, as well as accessory genes and encoded proteins. However, given the absence of a definition in the instant specification of the term accessory molecule, and given the divergent structures and functions of the accessory molecules disclosed (costimulatory molecules, adhesion molecules and survival molecules), the genus of said accessory molecules that would be effective in the recited method of producing an eucaryotic poikilothermic synthetic antigen presenting cell, would not be readily apparent to one of skill in the art, without further guidance from the specification. Thus with the exception of a method comprising the accessory molecules of B7.1, B7.2, ICAM-1, ICAM-2, ICAM-3, FASL, CD70 and LFA, there is inadequate written description for a method comprising the breadth of the accessory molecules encompassed by the instant claims, without further description from the specification.

MAINTAINED Claims 61-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a synthetic antigen presenting cell comprising an insect cell and the accessory molecules of B71.1, B71.2, ICAM-1, ICAM-2 ICAM-3, FASL, CD70 and LFA, does not reasonably provide enablement for said method comprising any cell, nor any accessory molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

### *Response to Arguments*

Applicant traverses the rejection on the grounds that every species encompassed by the claims need not be disclosed with which the examiner agrees. Applicant further contends that by selecting insect cells as the cell type in which to demonstrate in which to demonstrate how a synthetic antigen presenting cell is made and used, that the invention need not be so limited. However, the specification teaches the advantages of using insect cells in a method of producing a synthetic antigen presenting cell, said advantages including that MHC Class II molecules have been expressed in insect cells, and that insect cells do not have a mammalian peptide antigen loading machinery nor class II molecules, therefore allowing the introduced mammalian MHC class II molecules to be expressed as empty molecules at the cell surface, allowing specific peptides to be loaded into specific MHC Class II molecules at room temperature. However, the specification does not disclose that said advantages are transferable to a cell line from any eucaryotic poikilothermic organism, such as a higher poikilothermic organism such as fish or shark, whose peptide antigen loading system is not disclosed.

With regard to the scope of the accessory molecules, Applicant contends that antigen presentation mediated by MHC Class II molecules and accessory molecules is well known to one of ordinary skill in the immunological arts. However, given the lack of a precise definition of accessory molecules in the instant specification, and the accordingly broad scope of the accessory molecules known and unknown encompassed by the instant claims, and the lack of specific guidance regarding their function in any cell from any eucaryotic poikilothermic organism, it would require undue experimentation to predict the success of the recited method comprising any accessory molecule, other than those of B71.1, B71.2, ICAM-1, ICAM-2 ICAM-

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3, FASL, CD70 and LFA, and any cell other than an insect cell, without further guidance and direction from the instant specification.

WITHDRAWN Claims 61-82 are NO LONGER rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Conclusion**

No Claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.  
Patent Examiner,  
April 2, 2003

  
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